# GOVERNMENT OF INDIA
# HEALTH AND FAMILY WELFARE
# LOK SABHA

UNSTARRED QUESTION NO:1501
ANSWERED ON:04.03.2016
Delay in Clearance
Rao (Avnthi) Shri Muthamsetti Srinivasa

**Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:**

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether a project for the manufacture of life saving heart valves is held up since 2012 for lack of clearance, if so, the details thereof and the reasons therefor;

(b) whether people suffering from heart valve disease spend crores on importing expensive replacements from abroad every year, if so, the details thereof;

(c) whether an indigenously made bioprosthetic valve would make treatment accessible to thousands, if so, the details thereof; and

(d) the steps taken/being taken by the Government to clear the project in the backdrop of PM"s slogan "Make in India"?

## Answer

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)
(a): An application seeking permission under the Drugs and Cosmetics Rules, 1945 to develop and manufacture (i).Tissue Engineered Bovine Pericardium, (ii).Tissue Engineered Bovine Jugular Vein and (iii).Tissue Engineered Porcine Pulmonary Artery by M/s Frontier Lifeline, Chennai was received in the Central Drugs Standard Control Organization (CDSCO) on 19.05.2015. However, Phase III clinical trials to prove the safety and efficacy of these products have not yet been carried out by the applicant. Further, the protocol of Phase III clinical trial was deliberated upon in the meeting of the Cellular Biology Based Therapeutics Drugs Evaluation Committee (CBBTDEC) on 29.10.2015 under the Chairmanship of Director General, Indian Council Medical Research. The Committee has recommended to conduct the trial with control arm in non-vascularised bed with specific end points of safety and efficacy. The applicant has, however, not agreed to one of the recommendations of the Committee.

(b): Cost of imported bioprosthetic valves in India varies from Rs.75,000 to Rs.1.75 lakhs. Chitra-TTK valve is a mechanical valve which is indigenously manufactured in India. Cost of this valve is in the range of Rs.18,000/- to 20,000/-.
(c): Chitra-TTK valve is cheaper as compared to imported mechanical valves which cost around Rs.45,000/- to Rs.55,000/-. Indigenously made bioprosthetic valve could help in reducing the treatment cost to some extent.
(d): As stated in reply to part (a) above, clearances in the instant case have already been given.